510k: k090889 DEC - 4 2009

~~Section 5:~~ 510(k) Summary

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the EMSI Garment Electrodes is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices.

Applicant:	EMSI 3504 Cragmont Dr. Suite#100 Tampa, Florida 33619 Ph: 813-471-0129 Fax: 813-471-0130 Registration Number: 3003573572
Manufacturer:	Asiatic Fiber Corporation 11F, No. 166, Sec. 2, Fu Hsing S. Rd.,Taipei(106),Taiwan Phone : 886-2-27082136 Fax : 886-2-27082139
Contact:	Cherita James M Squared Associates, Inc 901 King Street, Suite 200 Alexandria, Virginia 22314 Phone: 703-562-9800 Ext. 257 Facsimile: 703-562-9797
Date of submission:	March 30, 2009
Proprietary Name:	EMSI Garment Electrodes
Common Name:	Cutaneous Electrodes Garment (CEG)
Classification Status:	Class II
Product Code:	GXY Cutaneous Electrodes
Panel:	Neurological Devices
Predicate Device:	EMSI Garment Electrodes are substantially equivalent, for the purpose of this 510(k), to other devices that have received 510(k) clearance for similar indications for use.
Intended Use:	Garment Electrodes that are applied directly to a patient's skin to

510k: k040899

apply electrical stimulation.

Indications for Use: Electrodes intended for use as reusable (by a single patient), cutaneous, flexible, conductive garment/fabric electrodes for interface between electrical stimulators such as interferential devices, galvanic devices, TENS, etc. and a patient's skin for the delivery of electrical stimulation.

Device Description: The EMSI Garment Electrodes are a cloth type device weft knitted of a continuous fiber made up of 77% Nylon and 23% Silver. Each device is flexible, and is available in a range of sizes to ensure good patient contact. A male snap connector is placed within the fabric weave and is connected via the female snap connector to a short lead wire. The lead wire has a female pin connection at the distal end which accepts the lead wire connection from the stimulator. The entire fabric is made up of conductive material to provide uniform current distribution when connected to a stimulator.

Discussion of performance testing: Biocompatibility confirms the EMSI Garment Electrode performs safely for its intended use. Bench testing demonstrated very low impedance to the treatment signals compared to the patient and the other electrode impedances in the circuit. Testing verified the garments to maintain performance specifications up to 30 wash cycles.

Technological Characteristics and Substantial Equivalence

The subject device is made up of similar fabrics and in similar configurations. The intended use and indications are identical to the predicate device. Comparison of surface and connector resistance of the subject and predicate device demonstrated the EMSI Garment Electrodes to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

M Squared Associates, Inc.
c/o Ms. Cherita James
Regulatory Consultant
901 King Street
Suite 200
Alexandria, VA 22314

DEC - 4 2009

Re: K090889
Trade/Device Name: EMSI Garment Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: II
Product Code: GXY
Dated: October 30, 2009
Received: November 2, 2009

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

~~Section 4:~~ Indications for Use Statement

510(k) Number: ~~To be assigned~~ K090889

Device Name: EMSI GARMENT ELECTRODE

Indications for Use: Electrodes intended for use as reusable (by a single patient), cutaneous, flexible, conductive garment/fabric electrodes for interface between electrical stimulators such as interferential devices, galvanic devices, TENS, etc. and a patient's skin for the delivery of electrical stimulation.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K090889